Premarket Notification [510(k)] Summary

SEP 2 9 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K061138

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Contact Person: Tim Lawton (tlawton@fr.abx.fr)

Date Prepared: 1st September 2006

Device Names:
The following reagents, controls & calibrators are for use in conjunction with the ABX PENTRA 400, cleared to market under K052007.

REAGENTS :

Trade/Proprietary Name:	**ABX PENTRA CRP CP**
Common or Usual Name:	C-Reactive Protein
Device Class	Class II
Classification Name:	§866.5270 : C-reactive Protein Immunological Test System
Product Code:	DCK ; C-Reactive Protein, Antigen, Antiserum and Control

CALIBRATORS:

Trade/Proprietary Name:	**ABX PENTRA CRP Cal**
Common or Usual Name:	CRP Calibrator
Device Class	Class II
Classification Name:	§866.5270 : C-reactive Protein Immunological Test System
Product Code:	DCK ; C-Reactive Protein, Antigen, Antiserum and Control

CONTROLS :

Trade/Proprietary Name:	**ABX PENTRA Immuno I Control L/H**
Common or Usual Name:	Multi-analyte Control
Device Class	Class I
Classification Name:	§862.1660 : Quality control material (assayed)
Product Code:	JJY ; Multi-Analyte Controls, All Kinds (assayed)

Trade/Proprietary Name:	**ABX PENTRA Low CRP Control**
Common or Usual Name:	CRP Control
Device Class	Class II
Classification Name:	§866.5270 : C-reactive Protein Immunological Test System
Product Code:	DCK ; C-Reactive Protein, Antigen, Antiserum and Control

CLEANING SOLUTIONS:

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem CP** (K052007)
Common or Usual Name:	Cleaning solution : Clean-Chem
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Trade/Proprietary Name:	**ABX PENTRA Clean-Chem 99 CP** (K052007)
Common or Usual Name:	Cleaning solution : Clean-Chem 99
Device Class	Class I : Exempt from Premarket
Classification Name:	Not available
Product Code:	Not available

Substantial Equivalence:

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

Submission device	Substantially equivalent Predicate device
ABX PENTRA CRP CP	K023828
ABX PENTRA CRP Cal	K023828
ABX PENTRA Immuno I Control L/H	K022486
ABX PENTRA Low CRP Control	K022486

Description:

All the reagents, controls and calibrators included in this submission are for use on the **ABX PENTRA 400** (K052007), which is a discrete photometric benchtop clinical chemistry analyzer.

The **ABX PENTRA CRP CP** is an in vitro diagnostic assay for the quantitative determination of C-reactive protein in human serum and plasma based on an immunoturbidimetric test. The assay is composed of a bi-reagent cassette, with 25 ml and 23.5 ml compartments. Reagents are chemical solutions with additives.

The **ABX PENTRA CRP Cal** is a liquid human serum calibrator with chemical additives. It has 5 levels to be used for the calibration of the crp assay. The assigned values are given on the calibrator vials. This calibrator is provided in five vials of 1 ml.

The **ABX PENTRA Immuno I Control L/H** is a lyophilized two-level quality control product consisting of human serum. The assigned values of the control components are given in the enclosed annex, ensuring control of the appropriate HORIBA ABX methods on the ABX PENTRA 400 analyzer. Each level of control is provided in one vials of 3 ml.

The **ABX PENTRA Low CRP Control** is a liquid assayed control prepared by diluting crp at low concentration in human serum. It has to be used for the quality control of low levels measured with the crp assay. The assigned value is given in the enclosed annex. This control is provided in four vials of 1 ml.

The **ABX PENTRA Clean-Chem CP** and **ABX PENTRA Clean-Chem 99 CP** are ready-to-use chemical cleaning solutions for use on the ABX Pentra 400 system. They are respectively provided in mono-reagent 30 ml and 4 x 99 ml cassettes.

Intended Use :

The reagent in this submission is intended for use on the **ABX PENTRA 400** for the quantitative in-vitro determination of conventional range crp using human serum and plasma.

The controls, calibrators and additional reagents are intended for use in association with the above reagent.

Discussion of Performance Data:

REAGENTS

ABX PENTRA CRP CP :	
Sample type	Serum & plasma
Detection limit	0.09 mg/l
Accuracy and Precision	Conventional range : CV Total < 7.04%
Measuring range	0.13 mg/l – 158.30 mg/l
Upper linearity limit	160 mg/l, and with automatic post-dilution : 800 mg/l
Correlation (n=190)	Y = 1.03 x - 0.18 with a correlation coefficient $r^2 = 0.997$.
Calibration stability	18 days
Reagent stability	Closed stability: 24 months at 2-10°C On-board stability (refrigerated area): 64 days

CALIBRATORS

ABX PENTRA CRP Cal:	
Analytes	C-Reactive Protein (CRP)
Format	Liquid human serum with chemical additives (preservatives) and materials of biological origin
Stability	Closed stability: 12 months at 2-10°C Open stability: 3 months at 2-10°C

CONTROLS

ABX PENTRA Immuno I Control L/H:	
Analyte	Multi-Analyte Control : ASO, CRP, RF 2 levels: Low and High
Format	Lyophilized pool of human sera with chemical additives (preservatives)
Stability	Closed stability: 24 months at 2-10°C Open stability: 2 weeks at 2-10°C 3 months at –20°C

ABX PENTRA Low CRP Control:	
Analyte	Single-Analyte Control : CRP
Format	Liquid human serum with chemical additives (preservatives) and materials of biological origin
Stability	Closed stability: 12 months at 2-10°C Open stability: 4 weeks at 2-10°C

CLEANING SOLUTIONS

ABX PENTRA Clean-Chem CP:	
Format	Chemical liquid solution
Stability	Closed stability: 8 months at 2-8°C On-board stability (refrigerated area): 15 days

ABX PENTRA Clean-Chem 99 CP:	
Format	Chemical liquid solution
Stability	Closed stability: 8 months at 2-8°C On-board stability (refrigerated area): 45 days

Conclusions for Performance Testing :
The performance testing data conclude that the safety and effectiveness of the devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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SEP 29 2006

Re: K061138

Trade/Device Name: C-Reactive Protein on ABX PENTRA 400 Clinical Chemistry Analyzer
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK, JIS, JJX, JJY
Dated: September 15, 2006
Received: September 20, 2006

Dear Mr. Lawton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061138

Device Name: C-Reactive Protein on ABX PENTRA 400 Clinical Chemistry Analyzer

Indications For Use:

CRP reagent, with associated calibrators and controls, are intended for use on ABX PENTRA 400 Clinical Chemistry Analyzer to measure C-reactive Protein analyte.

The ABX PENTRA CRP Cal is a calibrator for use in the calibration of quantitative Horiba ABX PENTRA CRP CP method on Horiba ABX clinical chemistry analyzers.

The ABX PENTRA Low CRP Control is for use in quality control by monitoring accuracy and precision for the quantitative ABX PENTRA CRP CP method.

ABX PENTRA CRP CP reagent with associated calibrators and controls are for quantitative in vitro diagnostic determination of the C-reactive protein in human serum and plasma based on an immunoturbidimetric assay.

The ABX PENTRA Immuno I Control L/H is for use in quality control by monitoring accuracy and precision for CRP.

Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K061138